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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,758

06/10/2005

Hiromu Habashita

Q88484

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65565 7590 11/26/2008  
SUGHRUE-265550  
2100 PENNSYLVANIA AVE. NW  
WASHINGTON, DC 20037-3213

EXAMINER

JARRELL, NOBLE E

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

11/26/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/538,758	<b>Applicant(s)</b> HABASHITA ET AL.	
	<b>Examiner</b> NOBLE JARRELL	<b>Art Unit</b> 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,6,8-10,17,19,23,28-30 and 33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6,8-10,17,19,28-30 and 33 is/are rejected.
- 7) ☒ Claim(s) 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/20/08</u> .   | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### ***Response to Arguments***

1. The rejections under 35 U.S.C. 112 1<sup>st</sup> and 2<sup>nd</sup> paragraph have been overcome by the amendment filed 8/22/2008.
2. The written description rejection has been overcome by the amendment filed 8/22/2008.
3. Priority is granted to December 10, 2002.

### ***Claim Objections***

4. Claims 8, 9 and 23 are objected to because of the following informalities: it contains non-elected material. Variable B can only be pyrimidine by itself within the elected group. The proviso of claim 8 contains non-elected compounds. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:  

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 1, 6, 9, 10, 17, 28-30, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In these claims, linker G between NH and ring J in variable Y is not clearly defined. A "spacer containing 1-3 atoms in the main chain" fails to define this variable because it is unclear for two reasons: one, what atoms are functioning in the spacer group; and two, is the spacer a chain or ring group? A chain of 2-3 atoms could also have a ring bonded to the atoms and the spacer can be cyclic. What substituents are intended for rings A and B and the hydrocarbon and heterocyclic groups for variable W? What hydrocarbon and heterocyclic groups are intended for variable W?

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***Double Patenting***

7. Claim 17 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Because the intended use in a compound claim has no patentable weight, claim 17 is considered a duplicate claim of claim 1.

8. Claims 19 and 23 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 8. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Because the intended use in a compound claim has no patentable weight, claims 19 and 23 are each considered a duplicate claim of claim 8.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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10. Claims 1, 6, 10, 17, and 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Bilodeau et al. (US20020137755, published 26 September 2002). Bilodeau et al. teach compound 25-4 (page 38) and compositions comprising the same (claim 10, page 62). In compound 25-4, variable A is 4-amino-azepane, ring B is pyrimidine, variable G is a bond, and variable J is 5-cyano-1,3-thiazole. A 5-cyano-1,3-thiazole ring is 5-membered nitrogen-containing ring.

11. Claims 1, 6, 10, 17, and 19 are rejected under 35 U.S.C. 102(e) as being anticipated by Bilodeau et al. (US20020137755, published 26 September 2002, claims priority to 60/251006, filed 4 December 2000). Bilodeau et al. teach compound 25-4 (page 38) and compositions comprising the same (claim 10, page 62). In compound 25-4, variable A is 4-amino-azepane, ring B is pyrimidine, variable G is a bond, and variable J is 5-cyano-1,3-thiazole. A 5-cyano-1,3-thiazole ring is 5-membered nitrogen-containing ring.

***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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14. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bilodeau et al. (US20020137755, published 26 September 2002. claims priority to 60/251006, filed 4 December 2000).

*Determining the scope and contents of the prior art*

Bilodeau et al. teach compound 25-4 (page 38) and compositions comprising the same (claim 10, page 62). In compound 25-4, variable A is 4-amino-azepane, ring B is pyrimidine, variable G is a bond, and variable J is 5-cyano-1,3-thiazole. A 5-cyano-1,3-thiazole ring is 5-membered nitrogen-containing ring.

*Ascertaining the differences between the prior art and the claims at issue*

In instant claim 8, the variable B (where it is pyrimidine) is substituted at the 2 and 4 positions. In compound 25-4 of Bilodeau et al., the pyrimidine ring I substituted at the 4 and 6 positions.

*Resolving the level of ordinary skill in the pertinent art*

One of ordinary skill recognizes that the pyrimidine rings of claim 8 and the pyrimidine ring compound 25-4 are positional isomers.

*Considering objective evidence present in the application indicating obviousness or nonobviousness*

*In re Norris* (84 USPQ 458) teaches: Novel and useful chemical compound, which is isomeric with compounds of prior art, is not patentable where new compound is not shown to possess new and unexpected utilities.

Because compound 25-4 of Bilodeau et al. is considered a positional isomer of instant claim 8 (and consequently structurally similar), it would be obvious to try compound 25-4 in the same method of use in the instant application.

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***Conclusion***

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NOBLE JARRELL whose telephone number is (571)272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Noble Jarrell/  
Examiner, Art Unit 1624

**/James O. Wilson/  
Supervisory Patent Examiner, Art Unit 1624**